

ORIGINAL

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COMMENTS: 8EFU

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2012 OCT 16 AM 10:33  
**AkzoNobel**  
Tomorrow's Answers Today

October 15, 2012

US EPA Office of Pollution Prevention and Toxics  
EPA East Building Room 6428  
Attn: Section 8(e)  
1201 Constitution Avenue, NW  
Washington, DC 20004



Cc: Polymer Chemicals bv  
Arkema France  
Pergan GmbH  
United Initiators GmbH & Co. KG

**SUBJECT: TSCA 8(e) Notice**



Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals LLC we are submitting terminal summary results on an OECD 422 Combined Repeat Dose Toxicity with Reproduction/Developmental Toxicity Screening Test, with 2,5-dimethyl-2,5-di(2-ethylhexanoylperoxy) hexane, (EC name: 1,1,4,4-tetramethylbutane-1,4-diylbis(2-ethylperoxyhexanoate) CAS# 13052-09-0. The study was sponsored by Akzo Nobel Polymer Chemicals bv.

Male and female rats were administered the test article by oral gavage at 0, 30, 300 and 1000 mg/kg bw/day, in Arachis oil BP. After eleven weeks of treatment, males and females were paired for a fourteen day mating period and females were maintained throughout gestation and allowed to rear their young to Day 5 of age.

Clinical signs, functional observations, body weight change, food and water consumption, female estrous cycles and ophthalmic evaluations were monitored during the study. Haematology and blood chemistry were evaluated for both sexes at the end of the study. All animals were subjected to gross necropsy examination, which included sperm analyses for males, and histopathological evaluation of selected tissues from high dose and control animals.

A previous TSCA 8(e) notice, 8EHQ-12-18714, was submitted on the interim results from this study. The current submission reports hematology, biochemistry and histopathology findings.

### **Hematology**

At 1000 mg/kg bw/day, lower mean cell hemoglobin concentration for both sexes attained statistical significance when compared with control. No other statistically significant differences from control were apparent for other erythrocyte parameters for these animals. Additionally, for males at 1000 mg/kg bw/day, faster prothrombin time and slower activated partial thromboplastin times attained statistical significance compared with control.

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### ***Biochemistry***

At 1000 mg/kg bw/day, lower bilirubin levels for both sexes attained statistical significance when compared with control. Additionally, for males at 1000 mg/kg bw/day, higher urea, potassium, calcium and phosphorus levels attained statistical significance when compared with control. For females at this dosage, higher total protein and albumen levels attained statistical significance compared with control; no statistically significant change in albumin/globulin ratio was apparent.

### ***Histopathology***

Centrilobular hepatocellular hypertrophy was recorded at moderate severities in several males dosed with 1000 mg/kg/day. Since this finding was not accompanied by further degenerative or inflammatory signs it is believed to be reversible and to represent an adaptive effect.

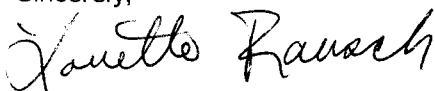
Hyaline droplet nephropathy, consisting of increased incidence and severity of hyaline droplets, tubular degeneration, granulated tubular casts and interstitial inflammatory infiltrate was recorded in males treated with 1000 mg/kg/day. This nephropathy is deemed to be related to treatment. Since the hyaline droplets in the male rat relate to accumulation of alpha2-micoglobulin, and little or none of this protein is present in man, a nephropathy in man that involves the same mechanism is unlikely to occur with the test item (Ref. 1, Greaves 2000), i.e. this finding is adverse for the male rat but has limited relevance for other species including man.

Increased incidence and severity of follicular hypertrophy was recorded in males and females treated with 1000 mg/kg/day. Follicular hypertrophy of the thyroids is deemed to be associated with the increased hepatic metabolism of thyroid hormones (T3/T4) due to hepatocellular hypertrophy in group 4. Therefore this finding is deemed to represent an effect secondary to hepatocellular hypertrophy.

All other parameters evaluated were deemed to be within normal background range. Additional histopathology and statistical analyses are currently being conducted on the lower dose groups.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.

Sincerely,



Louette Rausch  
Expertise Leader Regulatory Affairs Americas  
Akzo Nobel Services Inc.  
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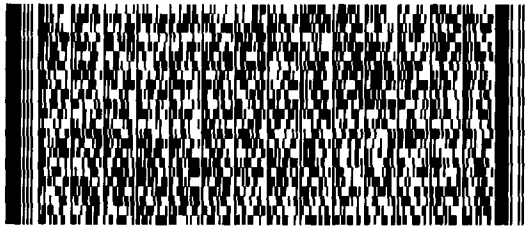
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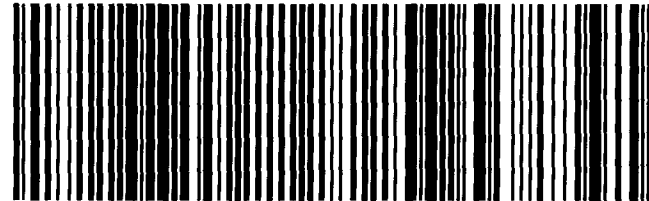
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